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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,261	12/03/2003	Herbert W. Harris	18184-0004 US	7783

23973 7590 07/27/2006

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EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/728,261	HARRIS ET AL.	
	Examiner	Art Unit	
	Kendra D. Carter	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) *13-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/3/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

From the election restriction dated May 17, 2006, the Applicant elected in the remarks dated June 8, 2006 Group I (claims 1-12) without traverse on the right to obtain rejoinder of all other claims. Therefore, the restriction is upheld and made final.

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 1-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 7, and 9-12 of U.S. Patent No. US 6,638,928 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons below.

The U.S. Patent No. US 6,638,928 B1 discloses a method of treating or preventing irritable bowel syndrome or nonulcer dyspepsia comprising administering an effective amount of at least one compound according to formula I, which may be either (R) or (S), or a pharmaceutically acceptable salt thereof (see claim 1). The compound of formula I wherein R^1 and R^2 is $(C_1\text{-}C_7)$hydrocarbyl, R^3 and R^4 are $O(C_1\text{-}C_7)$hydrocarbyl, R^5 is OH, and R^6 is $O(C_1\text{-}C_7)$hydrocarbyl, corresponds to the applicant's

compound 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine. In claim 12, US 6,638,928 B1 discloses a method comprising the applicant's specific compound stated above.

The U.S. Patent No. US 6,638,928 B1 does not disclose a composition of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine and in which the compound is in 85%, 90% or 95% by weight.

To one having ordinary skill in the art would find it obvious to formulate a composition of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine from the method of US 6,638,928 B1 because the method of treatment comprises administering the same compound, thus rendering the composition obvious. The weight percents of the composition would also be obvious because it is the normal desire of scientists or artisans to improve upon what is already generally known. In this case, US 6,638,928 B1 discloses that the compound of formula I be administered in a formulation between 0.1 to 99.91 weight percent (see column 17, lines 33-37). Thus, the composition of the (R) or (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine in 85%, 90% or 95% by weight is taught by US 6,638,928 B1.

2) Claims 1-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 7-12 of U.S. Patent

No. US 6,864,251 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons below.

The U.S. Patent No. US 6,864,251 B2 discloses a method of treating an inflammatory disorder mediated by LTB_4 comprising administering an effective amount of at least one compound according to formula I in its (R)-enantiomer substantially free of the corresponding (S)-enantiomer, or a pharmaceutically acceptable salt thereof (see claim 1). The compound of formula I wherein R^1 and R^2 are $(C_1\text{-}C_7)$hydrocarbyl, R^3 and R^5 are $O(C_1\text{-}C_7)$hydrocarbyl, n = 2, and R^4 is OH, corresponds to the applicant's compound 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine. In claim 5, US 6,864,251 B2 discloses a method comprising the applicant's specific compound stated above.

The U.S. Patent No. US 6,864,251 B2 does not disclose a composition of the (R) and (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine and in which the compound is in 85%, 90% or 95% by weight.

To one having ordinary skill in the art would find it obvious to formulate a composition of the (R) and (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine from the method of US 6,864,251 B2 because the method of treatment comprises administering the (R)-enantiomer of the same compound, thus rendering the composition obvious.

A composition of the racemic mixture or the (S)-enantiomer is obvious because the (R)-enantiomer is taught by US 6,864,251 B2. Stereoisomerism is well known to persons having ordinary skill in the art. A person having ordinary skill in the art would have been motivated to obtain the racemic mixture and the (S)-enantiomer with a reasonable expectation of achieving substantially different pharmacological activity.

The weight percents of the composition would also be obvious because it is the normal desire of scientists or artisans to improve upon what is already generally known. In this case, US 6,863,251 B2 discloses that the compound of formula I be administered in a formulation between 0.1 to 99.91 weight percent (see column 20, lines 59-64). Thus, the composition of the (R) and (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine in 85%, 90% or 95% by weight is taught by US 6,863,251 B2.

3) Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18, 23 and 29 of copending Application No. 10/461290.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons below.

The U.S. Application 10/461290 discloses a method of modulating domamine resposes in the central nervous system comprising administering an effective amount of at least one compound according to formula I in its (S)-enantiomer substantially free of the corresponding (R)-enantiomer, or a pharmaceutically acceptable salt thereof (see claim 1). The compound of formula I wherein R^1 and R^2 are $(C_1\text{-}C_7)$hydrocarbyl, R^3 and R^4 are $O(C_1\text{-}C_7)$hydrocarbyl, R^5 is OH, and R^6 is $O(C_1\text{-}C_7)$hydrocarbyl, corresponds to the applicant's compound 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine. In claim 33, 10/461290 discloses a method comprising the applicant's specific compound stated above.

10/461290 does not disclose a composition of the (R) and (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine and in which the compound is in 85%, 90% or 95% by weight.

To one having ordinary skill in the art would find it obvious to formulate a composition of the (R) and (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine from the method of 10/461290 because the method of treatment comprises administering the (S)-enantiomer of the same compound, thus rendering the composition obvious.

A composition of the racemic mixture or the (R)-enantiomer is obvious because the (S)-enantiomer is taught by 10/461,290. Stereoisomerism is well known to persons having ordinary skill in the art. A person having ordinary skill in the art would have been motivated to obtain the racemic mixture and the (R)-enantiomer with a reasonable expectation of achieving substantially different pharmacological activity.

The weight percents of the composition would also be obvious because it is the normal desire of scientists or artisans to improve upon what is already generally known. Thus, the composition of the (R) and (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine in 85%, 90% or 95% by weight is taught by10/461290.

4) Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9-13, 15, and 25-31 of copending Application No. 10/727,940.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons below.

The U.S. Application 10/727,940 discloses a method of treating an individual afflicted with an inflammatory disorder comprising administering an effective amount of at least one compound according to formula I in a racemic mixture of (R)- and (S)- (see claim 1) or the (R)-enantiomer substantially free of the corresponding (S)-enantiomer, or a pharmaceutically acceptable salt thereof (see claim 9). The compound of formula I wherein R^1 and R^2 are $(C_1\text{-}C_7)$hydrocarbyl, R^3 and R^5 are $O(C_1\text{-}C_7)$hydrocarbyl, n = 2, and R^4 is OH, corresponds to the applicant's compound 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine. In claim 7, 10/727,940 discloses a method comprising the applicant's specific compound stated above.

10/727,940 does not disclose a composition of the (R)- and (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine and in which the compound is in 85%, 90% or 95% by weight.

To one having ordinary skill in the art would find it obvious to formulate a composition of the (R) or (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine from the method of 10/727,940 because the method of treatment comprises administering the racemic mixture and the (R)-enantiomer of the same compound, thus rendering the composition obvious.

A composition of the (S)-enantiomer is obvious because the racemic mixture and the (R)-enantiomer is taught by 10/727,940. Stereoisomerism is well known to persons

having ordinary skill in the art. A person having ordinary skill in the art would have been motivated to resolve the racemic mixture with the reasonable expectation of achieving substantially different pharmacological activity.

The weight percents of the composition would also be obvious because it is the normal desire of scientists or artisans to improve upon what is already generally known. Thus, the composition of the (R) and (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine in 85%, 90% or 95% by weight is taught by 10/727,940.

5) Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8-12, 14-16, 23-25, 34 and 36 of copending Application No. 10/728,286.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.
Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons below.

The U.S. Application 10/728,286 discloses a method of increasing the absolute neutrophil count in an individual comprising administering an effective amount of at least one compound according to formula I in a racemic mixture of (R)- and (S)- (see claim 1)

or the (R)-enantiomer substantially free of the corresponding (S)-enantiomer, or a pharmaceutically acceptable salt thereof (see claim 8). The compound of formula I wherein R^1 and R^2 are $(C_1\text{-}C_7)$hydrocarbyl, R^3 and R^5 are $O(C_1\text{-}C_7)$hydrocarbyl, n = 2, and R^4 is OH, corresponds to the applicant's compound 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine. In claim 6, 10/728,286 discloses a method comprising the applicant's specific compound stated above.

10/728,286 does not disclose a composition of the (R)- and (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine and in which the compound is in 85%, 90% or 95% by weight.

To one having ordinary skill in the art would find it obvious to formulate a composition of the (R) or (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine from the method of 10/728,286 because the method of treatment comprises administering the racemic mixture and the (R)-enantiomer of the same compound, thus rendering the composition obvious.

A composition of the (S)-enantiomer is obvious because the racemic mixture and the (R)-enantiomer is taught by 10/728,286. Stereoisomerism is well known to persons having ordinary skill in the art. A person having ordinary skill in the art would have been motivated to resolve the racemic mixture with the reasonable expectation of achieving substantially different pharmacological activity.

The weight percents of the composition would also be obvious because it is the normal desire of scientists or artisans to improve upon what is already generally known. Thus, the composition of the (R) and (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine in 85%, 90% or 95% by weight is taught by 10/728,286.

6) Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9-21, and 30-31 of copending Application No. 10/827,839.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.
Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons below.

The U.S. Application 10/827,839 discloses a method of lowering body temperature of an individual comprising administering an effective amount of at least one compound according to formula I in its (R)-enantiomer substantially free of the corresponding (S)-enantiomer, or a pharmaceutically acceptable salt thereof (see claim 8). The compound of formula I wherein R^1 and R^2 are (C_1-C_7)hydrocarbyl, R^{3b}, R^{3c} and R^5 are O(C_1-C_7)hydrocarbyl, R^{3a} is H, and R^4 is OH, corresponds to the applicant's compound 1-(3,4-

dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine. In claim 6, 10/827,839 discloses a method comprising the applicant's specific compound stated above.

10/827,839 does not disclose a composition of the (R)- and (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine and in which the compound is in 85%, 90% or 95% by weight.

To one having ordinary skill in the art would find it obvious to formulate a composition of the (R) or (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine from the method of 10/827,839 because the method of treatment comprises administering the (R)-enantiomer substantially free of the corresponding (S)-enantiomer of the same compound, thus rendering the composition obvious.

A composition of the racemic mixture or the (S)-enantiomer is obvious because the (R)-enantiomer is taught by 10/827,839. Stereoisomerism is well known to persons having ordinary skill in the art. A person having ordinary skill in the art would have been motivated to obtain the (S)-enantiomer or the racemic mixture with the reasonable expectation of achieving substantially different pharmacological activity.

The weight percents of the composition would also be obvious because it is the normal desire of scientists or artisans to improve upon what is already generally known. Thus, the composition of the (R) and (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine in 85%, 90% or 95% by weight is taught by 10/827,839.

7) Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9-22, and 31 of copending Application No. 10/781,422.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.
Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons below.

The U.S. Application 10/781,422 discloses a method of lowering body temperature of an individual comprising administering an effective amount of at least one compound according to formula I in its (S)-enantiomer substantially free of the corresponding (R)-enantiomer, or a pharmaceutically acceptable salt thereof (see claim 8). The compound of formula I wherein R^1 and R^2 are $(C_1$-$C_7)$hydrocarbyl, R^{3b}, R^{3c} and R^5 are $O(C_1$-$C_7)$hydrocarbyl, R^{3a} is H, and R^4 is OH, corresponds to the applicant's compound 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine. In

claim 6, 10/781,422 discloses a method comprising the applicant's specific compound stated above.

10/781,422 does not disclose a composition of the (R)- and (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine and in which the compound is in 85%, 90% or 95% by weight.

To one having ordinary skill in the art would find it obvious to formulate a composition of the (R) or (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine from the method of 10/827,839 because the method of treatment comprises administering the (S)-enantiomer substantially free of the corresponding (R)-enantiomer of the same compound, thus rendering the composition obvious.

A composition of the racemic mixture or the (R)-enantiomer is obvious because the (S)-enantiomer of formula I is taught by 10/781,422. Stereoisomerism is well known to persons having ordinary skill in the art. A person having ordinary skill in the art would have been motivated to obtain the (R)-enantiomer or the racemic mixture with the reasonable expectation of achieving substantially different pharmacological activity.

The weight percents of the composition would also be obvious because it is the normal desire of scientists or artisans to improve upon what is already generally known.

Thus, the composition of the (R) and (S)-enantiomer of 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine in 85%, 90% or 95% by weight is taught by10/781,422.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER